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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,538

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Caius Rommens

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EXAMINER

FOX, DAVID T

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/607,538	Applicant(s) ROMMENS ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/4/07 & 1/28/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,44-55 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,44-55 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's Response

Applicant's response of 28 January 2008 has obviated the art rejection of claim 13. Applicant is notified that the paragraph numbers relied upon for basis of the amendments of 28 January 2008 are incorrect. Basis for newly amended claim 3 may be found in paragraph [0045], rather than [0047] as stated on page 5 of the response, bottom paragraph. Basis for newly submitted claim 60 may be found in paragraph [0212], rather than [0213] as stated on page 6 of the response, top paragraph.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Indefiniteness

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 is confusing in its recitation of "obtained from the plant of claim 3", since claim 3 is drawn to a method rather than a plant.

Written Description

Claims 3, 5, 44-55 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 2 of the Office action of 05 July 2007 for claims 3, 5, 13 and 44-55.

Applicant's arguments filed 28 January 2008 have been fully considered but they are not persuasive. Applicant urges that the amended claims all recite a particular consensus sequence and its corresponding function.

The Examiner maintains that claim 3 and dependents do not particularly recite the function associated with the sequence, since line 8 recites "an enzyme" rather than ---a virD2 enzyme--- as recited in claim 60. In addition, claim 58 recites "*at least one* point mutation" [emphasis added], thus encompassing a multitude of sequences which fall outside of the initially claimed consensus sequence.

More importantly, Applicant has failed to demonstrate that the claimed 17 base pair-long consensus sequence is necessary and sufficient for the claimed function of "promot[ing] and facilitate[ing] integration of the desired polynucleotide into the plant genome", wherein said consensus sequence "is a recognition site for a [virD2] enzyme", as recited in claims 3 and 60.

First, the claimed consensus sequence is only 17 base pairs long, and only specifies 9 nucleotides out of the 17; while the actual border sequence is 25 base pairs long.

Second, even the 24 base pair-long consensus border sequence taught by Rommens et al (2005, page 1339, column 2, penultimate paragraph) was not consistently associated with integrative function in almost half of the sequences evaluated (Ibid., and page 1340, Figure 1).

Finally, the instantly claimed 17 base pair-long sequence is found in a multitude of non-plant organisms and does not appear to be correlated with integrative function in those organisms or in plants, as discussed below.

Dunn et al (Accession No. AZ483608 available October 5, 2000) teach a mouse sequence with 100% identity to SEQ ID NO:93. Vierling et al (Accession No. AAQ45318 first available November 18, 1994 and revised March 25, 2003) teach a hepatitis B sequence with 100% identity to SEQ ID NO:93. AEOMICA INC (Accession No. ADC04079 available December 18, 2003; earliest priority document filed January 30, 2001) teach a human ion exchange gene sequence with 100% identity to SEQ ID NO:93.

Thus, Applicant has not demonstrated that the conserved sequence, i.e. SEQ ID NO:93, is correlated with function, as required by *Lilly* cited previously. Furthermore, Applicant has not demonstrated that a multitude of sequence variants of SEQ ID NO:93, as claimed in claim 58, would retain the claimed function.

Accordingly, the skilled artisan would not have recognized Applicant to have been in possession of the claimed invention at the time of filing.

Enablement

Claims 3, 5, 44-55 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods of using 25 base pair-long P-DNA borders from plants comprising the consensus sequence of SEQ ID NO:47 to transfer foreign DNA to the genome of heterologous plants, does not reasonably provide enablement for claims broadly drawn to the use of border

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sequences comprising SEQ ID NO:93 or a multitude of "point mutations" thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated for claims 3, 5, 13 and 44-55 on pages 2-3 of the Office action mailed 05 July 2005.

Applicant's arguments filed 28 January 2008 have been fully considered but they are not persuasive. Applicant urges that the claim amendments have obviated the enablement rejection.

The Examiner maintains that the claims remain broader than the exemplified consensus sequence, as stated above and previously, wherein the claims read on the use of sequences which are either insufficient for DNA transfer in at least half of the time per Rommens et al (2005), or which are not associated with DNA transfer in plants at all per the teachings of Dunn et al, Viera et al and AEOMICA INC.

Thus, undue experimentation would have been required by one skilled in the art to evaluate a multitude of non-exemplified consensus sequences and consensus sequence variants for their ability to effect integration of foreign DNA into plant genomes.

Furthermore, Applicant is directed to newly cited Hansen et al, who teach that the use of synthetic T-DNA borders, analogous to the instant "border-like" sequences, to transform plants is unpredictable.

Hansen et al teach that even when a 25 base pair sequence with complete identity to native T-DNA borders is utilized, illegitimate integration of the vector

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backbone (rather than the “desired polynucleotide”) occurs in at least half the time (see, e.g., page 30, second full paragraph; page 47, first full paragraph). Hansen et al also teach that the function of the left T-DNA border is poorly understood (see, e.g., page 47, first full paragraph). In the instant case, Applicant is only specifying 17 out of the 25 nucleotides, and even those 17 are variable at 8 positions. Thus, even more unpredictability in the integration of the desired polynucleotide (rather than the vector backbone) would occur in the instant situation. See also claim 58 as stated above.

Anticipation

Claim 59 is rejected under 35 U.S.C. 102(e) as being anticipated by McElroy et al (US 6,750,379 effectively filed 09 March 2000), as stated on page 5 of the Office action mailed 05 July 2007, and as stated on pages 7-8 of the Office action mailed 20 November 2006, for claim 13.

The claim is broadly drawn to a progeny plant which comprises a “desired polynucleotide”, wherein the desired polynucleotide was originally introduced by flanking plant-derived P-DNA borders (or “border-like” sequences). However, these border sequences are partially or completely cleaved from the desired polynucleotide before the integration of the latter into the plant genome. Thus, the initially transformed plant or any progeny plant therefrom would be indistinguishable from any transformed plant containing a “desired polynucleotide” and not flanked by T-DNA borders, including the transformed plant taught by McElroy et al.

Conclusion

Claims 3, 5, 44-55, 58 and 60 are free of the prior art, for the reasons presented on page 6 of the Office action of 05 July 2007 for claims 3, 5 and 44-55.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 7, 2008

/David T Fox/

Primary Examiner, Art Unit 1638